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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543,174	07/22/2005	Gerard Remkes	2565/132	7919

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EXAMINER	
CHRISTIAN, MARJORIE ELLEN	
ART UNIT	PAPER NUMBER
1797	
MAIL DATE	DELIVERY MODE
12/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/543,174	REMKES ET AL.	
	Examiner	Art Unit	
	MARJORIE CHRISTIAN	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *1-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/22/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. This is the initial Office action based on the application filed July 22nd, 2005.

2. Claims 16-30 are pending and have been fully considered, claims 1-15 have been cancelled by Applicant.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Interpretation Under 35 USC § 112, 6th paragraph

4. Claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis: (A) the claim limitations must use the phrase "means for" or "step for; "(B) the "means for" or "step for" must be modified by functional language; and (C) the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function (MPEP § 2181). Five separate limitations meet the 3-prong test for interpretation under 35 U.S.C. 112, sixth paragraph:

- ***means for*** providing water in claim 23, (see Fig. 1, Ref. 38, W);
- ***means for*** mixing in claims 23, 26 and 28, (see 15, 17, 18, 20);
- ***means for*** conducting the dialysing fluid in claim 23, (see 11);
- ***means for*** discharging claim 27, (see 26, 28; 30, 31); and

- ***means for*** inputting data claim 30, (see 25).

For the purposes of examination, the Examiner will consider these limitations as invoking 35 U.S.C. 112, sixth paragraph.

Claim Rejections - 35 USC § 102

5. **Claims 16-30 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,744,027, CONNELL et al. (hereinafter CONNELL).**

As to Claim 16, CONNELL discloses a method for supplying a dialyser with a dialysing fluid (Abstract), comprising: dialysing fluid concentrate in a receiving unit (Figs. 1A-B, Refs. 126, 128); water for diluting the dialysing fluid concentrate (82); mixing the dialysing fluid concentrate and the water in pre-set volumetric ratio (C16/L45-48); and supplying the dialysing fluid (206) to the dialyser (Fig. 1A), supplied at a pre-set dialysing fluid flow rate over a pre-set treatment time (C16/L49-54 & C17/22-25); where the pre-set dialysing fluid flow rate is set at a value which depends upon the volume of the dialysing fluid concentrate at a commencement of treatment, volumetric ratio (C17/L1-15), and treatment time (C18/L18-20), at the end of the dialysis treatment the receiving unit is empty (C17/L33-44).

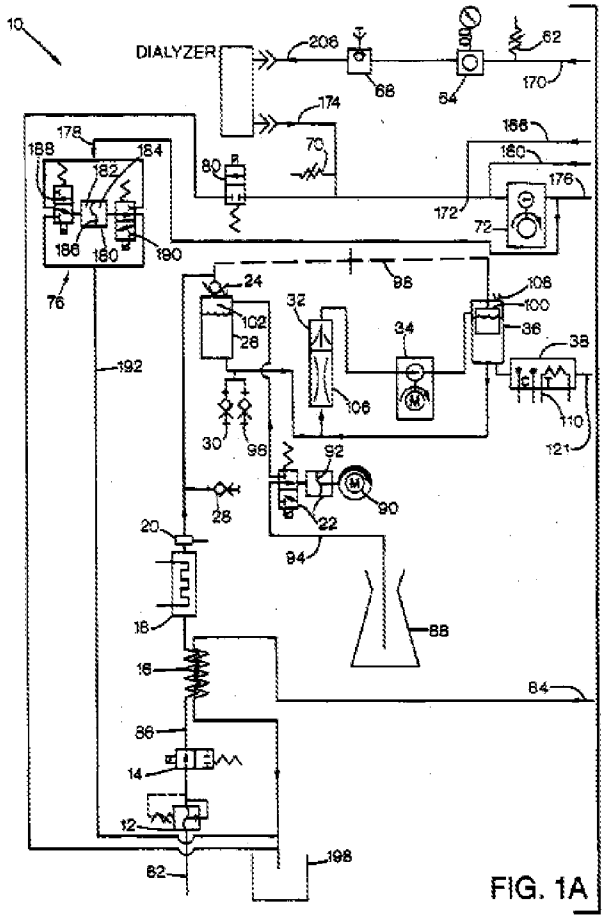

FIG. 1A

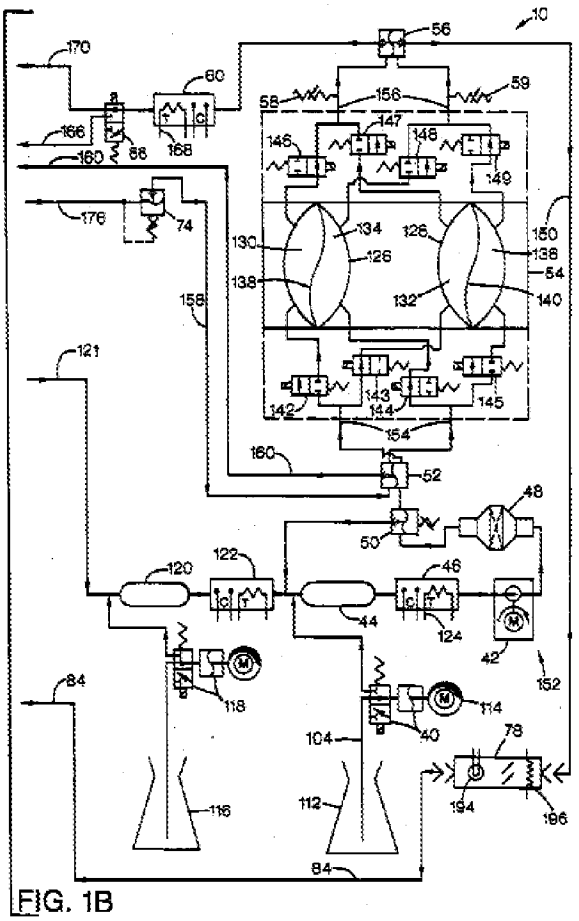

FIG. 1B

As to Claim 17, CONNELL discloses determining the flow rate before dialysis treatment from the volume of the dialysing fluid concentrate at the commencement of the dialysis treatment, volumetric ratio (C17/L1-15), and treatment time (C18/L18-20); wherein at the end of the treatment time the receiving unit is empty (C17/L33-44).

As to Claim 18, CONNELL discloses testing the dialysis unit before dialysis, comprising determining a volume of the dialysing fluid concentrate in the receiving unit before dialysis (C25/L51-55) from the volume of dialysing fluid concentrate at the commencement of the dialysis and dialysing fluid concentrate used during the time interval (C25/L64-C26/L6).

As to Claim 19, CONNELL discloses determining a dialysing fluid flow rate over a time interval of the dialysis treatment (C26/L19-36) where the dialysing fluid concentrate remaining in the receiving unit at the end of the dialysis treatment can be calculated from the volume of concentrate at the commencement of dialysis and amount of concentrate used during dialysis (C27/L21-61); and determining a dialysing fluid flow rate from a volume of the dialysing fluid concentrate in the receiving unit at the end dialysis, volumetric ratio (C17/L1-15), and remaining dialysis treatment time (C18/L18-20), wherein the dialysing fluid flow rate is the flow rate required for the remaining dialysis treatment time to ensure that at the end of dialysis the receiving unit is empty (C17/L33-44).

As to Claim 20, CONNELL discloses at the end of treatment the receiving unit (126, 128) contains the residual volume of the dialysing fluid concentrate (88, 112), the method further comprising: discharging the pre-set residual volume of the dialysing fluid concentrate to waste (66, 166 & C21/L53-62, C6/L39-46).

As to Claim 21, CONNELL discloses diluting the residual volume of the dialysing fluid concentrate with water in a second volumetric ratio before the residual volume is discharged to waste (C7/L57-67), where dialysate removed from the recirculation loop is sent to the drain (198).

As to Claim 22, CONNELL discloses at the end of the pre-set treatment time the receiving unit is empty (C17/L33-37).

As to Claim 23, CONNELL discloses an apparatus for supplying a dialyser of a dialysis unit with a dialysing fluid (Abstract, Fig. 1A-B), comprising: receiving unit for dialysing fluid concentrate (Fig. 1B, Ref. 126, 128); *means for* providing water (82); *means for* mixing the dialysing concentrate and water in a volumetric ratio to prepare the dialysing fluid (C2/L58-65, 22, 40, 42, 12); *means for* conducting the dialysing fluid to the dialyser (Fig. 6, Ref. 206) at a pre-set dialysing fluid flow rate and treatment period (C17/L20-47); and a control and calculating unit (516) designed such that a dialysing fluid flow rate Qd can be adjusted during a dialysis treatment, where at the end of dialysis the receiving unit is empty (C17/L33-44); wherein the dialysing fluid flow rate Qd is dependent upon a pre-set volume of the fluid concentrate, pre-set volumetric ratio (C17/L1-15), and the treatment period (C18/L18-20).

As to Claim 24, CONNELL discloses the control and calculating unit (516) is designed such that a dialysing fluid flow rate Qd_b is determined before dialysis from the pre-set volume of concentrate, pre-set volumetric ratio (C17/L1-15), and the treatment period (C18/L18-20), where it would naturally flow that the dialysing fluid flow rate Qd_b *is capable of* adjustment over the pre-set treatment period such that at the end of treatment the receiving unit is empty, absent evidence to the contrary.

As to Claim 25, CONNELL discloses the control and calculating unit (516) is designed such that a volume of concentrate in the receiving unit (126, 128) can be determined from the pre-set volume of concentrate at the commencement of treatment and a volume of concentrate used during the pre-set time interval (C17/L22-47), where it naturally flows that the purpose is for a test of the apparatus (i.e. calibration).

As to Claim 26, CONNELL discloses the control and calculating unit (516) operates in association with the *means for* mixing (C2/L58-65, 22, 40, 42, 12), such that during a time interval of the dialysing treatment a fluid flow is set (C26/L19-36) such that dialysing fluid concentrate remains in the receiving unit at the end and can be determined from the volume of the dialysing fluid concentrate at the commencement and amount of the dialysing fluid concentrate used during dialysis (C27/L21-61), and at the end of treatment, a fluid flow rate is determined from a volume of concentrate in the receiving unit at the end of treatment, volumetric ratio (C17/L1-15), and remaining dialysis time (C18/L18-20), wherein the dialysing fluid flow rate is the flow rate required for the remaining dialysis treatment time to ensure that at the end of dialysis the receiving unit is empty (C17/L33-44).

As to Claim 27, CONNELL discloses *means for* discharging the pre-set residual volume of the dialysing fluid concentrate to waste via a waste discharge outlet (66, 166); at the end of the treatment period the receiving unit contains the pre-set residual volume of the dialysing fluid concentrate (C17/L32-37), and the control and calculating unit (516) operates in association with the *means for* discharging (C21/L53-62). Where it naturally flows that at the end of the treatment period, the pre-set residual volume *is capable of* being discharged to the waste discharge outlet, absent evidence to the contrary.

As to Claim 28, CONNELL discloses *means for* mixing the pre-set residual volume of the dialysing fluid concentrate with water in a second pre-set volumetric ratio (C2/L58-65, 22, 40, 42, 12); wherein the control and calculating unit (516) operates in

association with the *means for* mixing, where it naturally flows that the pre-set residual volume is *capable of* being diluted with water before the pre-set residual volume is discharged to the waste discharge outlet (66, 166).

As to Claim 29, CONNELL discloses at the end of the pre-set treatment period the receiving unit is empty (C17/L33-37).

As to Claim 30, CONNELL discloses *means for* inputting data relevant to the pre-set volume of dialysing fluid, volumetric ratio, and treatment period (Figs. 7-11).

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- US PGPub 2002/0023880, PEDRINI et al., as it discloses a method of purifying blood by controlling infusion rates of substitution fluids;
- WO98/50091, DROZ et al., as it discloses method and apparatus for controlling a dialysis device including substitution fluids; and
- US Patent No. 4,386,634, STASZ et al., as it discloses a proportioning system for dialysate fluid including use of concentrate and dilution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJORIE CHRISTIAN whose telephone number is (571)270-5544. The examiner can normally be reached on Monday through Thursday 7-5pm (Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on (571)272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MC

/Krishnan S Menon/
Primary Examiner, Art Unit 1797